

Application No.: 10/821335

Case No.: 58562US005

REMARKS

Claims 1-51 are pending. Claims 10 and 15-51 have been withdrawn from consideration. Consequently, Claims 1-9 and 11-14 remain under consideration.

The specification has been amended to update identifying information of certain references. No new matter is introduced by these amendments.

§ 112 Rejections

Claims 1-6 and 11 stand rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

Specifically, the Office Action states that Applicants' claims are drawn to complexes that include an IRM compound that is an agonist of at least one TLR, and while the specification states in words that certain IRM compounds are agonists of particular TLRs, the specification "gives no evidence" that cited IRM compounds possess the claimed TLR agonism properties.

Applicants respectfully traverse the rejection. Compounds included in the classes recited in Applicants' disclosure from page 14, line 10 through page 15, line 6 were well established to be TLR agonists as of Applicants' priority date. Applicants are under no obligation to provide evidence for facts well established in the art.

The Office Action also appears to object to a lack of correlation between functional language recited in the rejected claims and chemical structure. A specific response to the rejection is difficult because the text cited in italics and between quotes in the Office Action is not found, as quoted in the Office Action, in Applicants' claims or disclosure. However, a general response to the rejection follows.

The Office Action states, "The functional language recited without any correlation does not meet the written description requirement..." Applicants assume that the correlation deemed to be deficient in this rejection is a correlation between the function of TLR agonism and chemical structure. Applicants provide ample description of chemical structure in the recitation of chemical classes of suitable IRM compounds and the recitation of specific IRM compounds at, for example, from page 13, line 28 through page 16, line 25.

The Office Action further states, "...one of skill in the art could not recognize or understand which diseases/disorders are treated by the mere recitation of the function." To fulfill

Application No.: 10/821335

Case No.: 58562US005

the written description requirement, the specification must describe the invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is *claimed*.

What is claimed is an IRM-support complex comprising an IRM compound attached to a macromolecular support material. Applicants describe suitable IRM compounds at, for example, from page 11, line 26 through page 16, line 26; suitable macromolecular support materials at, for example, from page 18, line 26 through page 23, line 28; and methods for attaching the IRM compound to the macromolecular support material at, for example, from page 27, line 18 through page 34, line 20. Applicants further provide specific embodiments of the claimed IRM-support complexes throughout the examples. Applicants submit that the claimed invention is fully described in Applicants' disclosure.

In summary, Applicants submit that the rejection of claims 1-6 and 11 under 35 USC § 112, first paragraph is improper and that the rejection should be withdrawn.

§ 102 Rejections

Claims 1-9 and 11-14 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,689,338 ("Gerster"). Gerster teaches IRM compounds formulated in polyethylene glycol.

The rejected claims recite an IRM-support complex comprising an IRM compound attached to a macromolecular support material. M.P.E.P. § 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (quoting *Verdegaal Bros. V. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Applicants submit that Gerster fails to set forth each and every element of the claims. Specifically, Gerster fails to set forth an IRM compound attached to a macromolecular support material.

Applicants describe the subject matter of the rejected claims at page 21, lines 9-13:

...the IRM is *not simply dissolved or blended into a formulation* from which it is to be released, but is *attached* to the support material by a sufficiently strong bond (which sometimes may require a covalent bond) so that under the circumstances of intended use the IRM is biologically active during use while it is attached to the support. (emphasis added)

Application No.: 10/821335

Case No.: 58562US005

This portion of Applicants' disclosure describes complexes that are specifically distinguished from the formulations described in Gerster and described in the same terms recited in the claims (i.e., attached). The concept of attachment, as used in present claims, is further discussed from page 8, line 32 through page 9, line 9:

Although the IRM may eventually detach from the macromolecular support material (e.g., through biodegradation of a polymer to which the IRM is attached, for example), *the IRM does not detach during a suitable period of use while it is active* (although it may of course also be active after detachment). Such attachment of an IRM to a macromolecular support material can be used to reduce the occurrence of, or prevent, the systemic absorption of the IRM, and can minimize the systemic side effects sometimes observed with the systemic administration of an IRM. Also, such attachment of an IRM to a substrate can serve to limit or focus the effect of the IRM to a localized region for a desired duration, and if the support material can be removed, the IRM can then be easily removed at will along with it. This provides very important control over where and how long the IRM is applied. (emphasis added)

The Office Action cites a statement in Applicants' disclosure (page 21, lines 16-20) as describing how the claimed complexes are made, states that the cited portion of Applicants' disclosure teaches that the claimed IRM-support complexes may be made by mixing and blending, and further asserts that this very same teaching is present in Gerster. Applicants respectfully submit that the Office Action misconstrues Applicants' disclosure.

Contrary to the Assertion made in the Office Action, the cited passage does not teach how the *claimed* complexes are made. The description relied upon in the Office Action is irrelevant to the rejected claims. As already noted, the rejected claims recite complexes in which an IRM compound is *attached* to a macromolecular support material. The cited portion of Applicants' disclosure pertains to embodiments in which "an IRM may be provided in an *unattached*, releasable form..." (page 21, lines 17-21, emphasis added). The cited portion of Applicants' disclosure therefore has no bearing on the rejected claims directed to complexes in which the IRM compound is attached to a macromolecular support material.

Gerster fails to set forth an IRM compound attached to a macromolecular support material. Therefore, Gerster fails to set forth each and every element of the claims. Thus, the rejection of claims 1-9 and 11-14 under 35 USC § 102(b) as being anticipated by Gerster is improper and should be withdrawn.

Application No.: 10/821335

Case No.: 58562US005

§ 103 Rejections

Claims 1-9 and 11-14 stands rejected under 35 USC § 103(a) as being unpatentable, presumably over any one of Gerster, U.S. Pat. No. 6,245,776 ("the '776 patent"), or International Patent Publication No. WO 2003/045391 ("the '391 application").

Applicants submit that the present rejection fails to establish a *prima facie* case of obviousness. M.P.E.P. § 706.02(j) states that to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference(s) or combine the reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art references must teach or suggest all of the claim limitations.

Applicants submit that the Office Action fails to establish a *prima facie* case of obviousness because each of the cited references, as well as any combination of the cited references, fails to teach or suggest all of the limitations of the rejected claims. The rejected claims are drawn to an IRM-support complex comprising an IRM compound attached to a macromolecular support material. None of Gerster, the '776 patent, and the '391 application teaches or suggests an IRM-support complex in which an IRM compound is attached to a macromolecular support material.

As discussed above, Gerster fails to set forth, teach, or suggest an IRM-support complex in which an IRM compound is attached to a macromolecular support material. Neither the '776 patent nor the '391 application provides any teaching or suggestion to correct the deficiencies of Gerster. None of the cited references, alone or in combination with any or all of the other references teaches or suggests an IRM-support complex in which an IRM compound is attached to a macromolecular support material. Consequently, the cited references fail to teach or suggest all of the claim limitations and, therefore, fail to establish a *prima facie* case of obviousness.

The rejection of claims 1-9 and 11-14 under 35 USC § 103(a) as being unpatentable over any one of Gerster, the '776 patent, and the '391 application is improper and should be withdrawn.

Application No.: 10/821335

Case No.: 58562US005

Double Patenting Rejections

Claims 1-9 and 11-14 stand provisionally rejected under nonstatutory obviousness-type double patenting. Applicants will provide an appropriate response to this provisional rejection upon indication of otherwise allowable subject matter.

Conclusion

In view of the above, Applicants submit that the application is in condition for allowance. Reconsideration of the application is requested.

Allowance of claims 1-9 and 11-14 at an early date is solicited.

Respectfully submitted,

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